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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,928	01/17/2007	Kiyoteru Shima	712-051	4833
47888 7590 12/12/2007 HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER NIA, ALIREZA	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding. .

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/557,928

Applicant(s)

SHIMA ET AL.

Examiner

Alireza Nia

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. PCT/JP04/05854.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/18/05:03/22/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract as currently disclosed in the application exceeds 150 words.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Claim Objections

2. Claim 1 is objected to because of the following informalities: on line 7, the term "an" should be -- a --. Appropriate correction is required.
3. With respect to the recitations "the external forceps channel for the endoscope" in lines 3 of each of claims 5, 6, 7, and 9, the language used by the applicant seems inconsistent with the previous recitations "external forceps channel device for an endoscope" in claims 1, 2, and 8. For the purpose of compact prosecution, the examiner has construed the "the external forceps channel" separately from the "endoscope" in the said recitation in lines 3 of each of claims 6, 7, and 9. Appropriate correction is required if the applicants' intention regarding the recitations in claims 5, 6, 7, and 9 is to be consistent with the said recitations in claims 1, 2, and 8.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With respect to claim 1, the recitation "together with the whole external forceps channel itself in a state where..." is unclear and vague.

7. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

8. Claim 6 recites the limitation "according to claim 1 or 5" in line 1 and 2 as well as "the rod guide portion" on line 4 and "the protruding guide" on line 6. If claim 6 depends from claim 1, there is insufficient antecedent basis for these limitations in the claim.

9. Furthermore, the recitations on lines 4-8 in claim 6 are unclear and vague. For the purpose of compact prosecution, the claim is examined as best understood by the examiner.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 1, 5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik 2004/0230095 in view of Cooper 4,667,229.**

12. With respect to claim 1, Stefanchik discloses an external forceps channel device for an endoscope 20 [0035], provided with an external forceps channel 50 which is capable of being repeatedly inserted and extracted via 40 [0036] in a way of being guided by a guide 30 provided on an endoscope 100 separately and independently therefrom along an outside of an insertion portion of the endoscope 100 via 27 [0039,0040] while using the endoscope 100 without drawing it out [0043]. Stefanchik further discloses a maneuvering portion 25 [0035,0048], characterized in that provided is the external forceps channel 50 capable of repeatedly extracting a foreign substance in a way of being guided by the guide 30 [0035] along the outside of the endoscope 100, together with the whole external forceps channel 50 itself in a state where the foreign substance is grasped by forceps 71 (fig. 9) inserted through the external forceps channel 50, and that provided is the external forceps channel 50 capable of being repeatedly inserted in a way of being guided via 40 by the guide 30 along the outside of the endoscope 100 in a state where the endoscope is not drawn out [0043].

13. However, Stefanchik does not positively disclose the endoscope incorporates an air supply path, a light source, a CCD camera, and a forceps channel.

14. Cooper teaches an air supply path (col. 3, lines 29,30), a light source 70, a CCD camera (col. 4, lines 1-2 and col. 5, lines 45-47), and a forceps channel (col. 3, line 30).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of the limitations taught by Cooper in order to provide a color video endoscope system for use in displaying an image from inside a cavity onto a monitor which includes an endoscope having means for identifying certain endoscope-specific characteristics, as taught by Cooper (col. 1, lines 46-50).

16. With respect to the recitation "the external forceps channel capable of repeatedly extracting a foreign substance larger than a bore diameter of the incorporated forceps channel", although Stefanchik does not positively recite the size of the diameter of the external forceps channel, for the intended purpose of extracting large specimens from the body via the external forceps channel using forceps, it would have been obvious to one of ordinary skill in the art at the time of the invention to have enlarged the diameter of the external forceps channel such that a large substance or specimen could easily pass through it, since it has been held that, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

17. With respect to claim 5, Stefanchik in view of Cooper disclose the invention as discussed above. Stefanchik further teaches the external forceps channel 50 for the endoscope 100 is provided either in such a manner that a groove 30 having a cross-section of a C-shape (figs. 1,2C) is provided along a surface of the insertion portion of the endoscope 100 via 27 in its longitudinal direction, and the external forceps channel 50 connected with a rod guide 40,140 which is insertable into and detachable from the C-shaped-cross-section 30 groove while sliding therealong, is provided *or* in such a manner that a protruding guide member is provided along the surface of the insertion portion of the endoscope 100 via 27 in its longitudinal direction (fig. 2B), and the external forceps channel 50 connected with the rod guide portion 40,140 which is insertable into and detachable from the guide member 30 while being guided by the guide member 30, is provided.

18. With respect to claim 7, Stefanchik in view of Cooper disclose the invention as discussed above. Stefanchik further teaches, for the external forceps channel 50 for the endoscope 100, an

open portion 132 of any of the C-shaped-cross-section groove 30 and the protruding guide member 25 is formed to have an elastic constrictive structure [0035] to prevent the external forceps channel 50 from protruding out (figs. 1,2C), the external forceps channel 50 being connected with the rod guide portion 40,140 slidably inserted into any of the C-shaped-cross-section groove 30 and the protruding guide member.

19. With respect to claim 9, Stefanchik in view of Cooper disclose the invention as discussed above. Stefanchik further teaches for the external forceps channel 50 for the endoscope 100, a cross-section 132 of the guide portion 30 connected with the external forceps channel 50 is formed into a C-shape 30 (figs. 1,2C), and a rail 132,140 is provided in any of the C-shaped-cross-section groove 30 and the protruding guide member 25 which are to be engaged with the C-shaped-cross-section guide portion 30 (figs. 1,2C).

20. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik 2004/0230095 in view of Cooper 4,667,229 in view of Ishikawa 6,071,233 further in view of Schendel 6,277,094.

21. With respect to claim 2, Stefanchik in view of Cooper disclose the invention as discussed above. Stefanchik further discloses the external forceps channel device for an endoscope 20 is an external forceps channel device capable of being slidably fitted along the outside of the insertion portion of an existing endoscope 100 via 27 [0035]. Stefanchik also discloses a tube having flexibility with a cross-section of a C-shape being fixed to a side of a fitting piece [0035].

22. However, Stefanchik in view of Cooper do not disclose detachable notched ring-shaped fitting pieces to be provided on an outer peripheral surface of the insertion portion at given intervals, a linear member having flexibility and elasticity being fixed to one end side of the fitting pieces to interconnect the fitting pieces, and the external forceps channel to be connected

with a rod guide portion that is slidably insertable into and detachable from the C-shaped cross section tube being provided in the C-shaped cross section tube.

23. Ishikawa teaches a detachable notched ring-shaped fitting piece 63 provided on an outer peripheral surface of an insertion portion at a given interval, a linear member 62 being fixed to one end side of the fitting piece 63 to be interconnected (col. 6, lines 30-45).

24. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of Cooper, further in view of the limitations taught by Ishikawa in order to provide an endoscope capable of continuously cutting or picking up a plurality of polyps present in the body cavity by means of an operating tool while leaving the endoscope in the body during a series of cutting-out operations for plurality of polyps, as taught by Ishikawa (col. 1, lines 30-35).

25. Stefanchik in view of Cooper in view of Ishikawa disclose the invention as discussed above. However, Stefanchik in view of Cooper in view of Ishikawa do not disclose the external forceps channel to be connected with a rod guide portion that is slidably insertable into and detachable from the C-shaped cross section tube being provided in the C-shaped cross section tube.

26. Schendel teaches an external forceps channel 61 to be connected via 53 with a rod guide portion 52 that is slidably insertable into and detachable from a C-shaped-cross-section tube being provided in a C-shaped-cross-section tube (col. 4, lines 38-55 et seq. 63-64).

27. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of Cooper in view of Ishikawa, further in view of the limitations taught by Schendel in order to provide an endoscopic apparatus having a radially flexible clip coupled to the insertion portion of the endoscope in order to selectively

provide or exchange working channels with variable cross-sections while the insertion portion is within the patient's body.

28. With respect to claim 4, Stefanchik in view of Cooper in view of Ishikawa in view of Schendel disclose the invention as discussed above. Stefanchik further discloses a guide portion 63 to be formed by cutting a ring obliquely from tip toward a base portion (fig. 3B, [0054]), and a positioning cap 55 [0052-0054] to match with the shape of a guide portion and is fitted on a tip of the insertion portion of endoscope 100.

29. However, Stefanchik in view of Cooper in view of Ishikawa in view of Schendel do not disclose a guide ring fitted on a tip of an external forceps channel device for an endoscope to be formed into a shape having a protruded center.

30. Ishikawa further teaches a guide ring 52 on a tip of an external channel device formed into a shape having a protruded center 51 (col. 5, lines 33-34).

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of Cooper in view of Ishikawa in view of Schendel, further in view of the limitations taught by Ishikawa in order to provide an endoscope capable of continuously cutting or picking up a plurality of polyps present in the body cavity by means of an operating tool while leaving the endoscope in the body during a series of cutting-out operations for plurality of polyps, as taught by Ishikawa (col. 1, lines 30-35).

32. With respect to the recitation "the guide ring on the tip of the external forceps channel device for an endoscope is positioned by aligning the guide ring on the tip of the device with the positioning cap fitted on the tip of the endoscope, at the tip of the endoscope when the external forceps channel device for an endoscope is inserted", in order for the externally provided channel to be readily used together with a conventionally employed endoscope system and operating

tools and to ensure the proper forward/backward movement of a forceps tool through the channel without obstructing the view field of the endoscope, it would have been obvious to one of ordinary skill in the art at the time of the invention to have aligned the guide ring on the tip of the device with the positioning cap fitted on the tip of the endoscope upon insertion of the external forceps channel device, since it has been held that rearranging parts of an invention involves only routine skill in the art, *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

33. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik 2004/0230095 in view of Cooper 4,667,229 in view of Ishikawa 6,071,233 in view of Schendel 6,277,094 further in view of Ogura 2002/0099266.

34. Stefanchik in view of Cooper in view of Ishikawa in view of Schendel disclose the invention as discussed above. However, Stefanchik in view of Cooper in view of Ishikawa in view of Schendel do not disclose the linear member to be any of a tension coil spring with no hook on either end and a rod member made of thermoplastic resin having flexibility and elasticity such as nylon material.

35. Ogura teaches a linear member being any of a tension coil spring 36 [0074] with no hook on either end and a rod member 34 [0067] having flexibility and elasticity.

36. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of Cooper in view of Ishikawa in view of Schendel, further in view of the limitations taught by Ogura in order to provide an endoscope system offering excellent maneuverability and making it possible to readily achieve accurate observation or treatment, as taught by Ogura [0013].

37. With respect to the recitation "a rod member made of thermoplastic resin having flexibility and elasticity such as a nylon material", it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a thermoplastic resin material such as polyamide or fluoroplastics (PTFEs) to make a durable and flexible rod member in order to avoid breakage or fracture of the rod member since it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

38. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik 2004/0230095 in view of Cooper 4,667,229 further in view of Schendel 6,277,094.

39. Stefanchik in view of Cooper disclose the invention as discussed above. However, Stefanchik in view of Cooper do not disclose the external forceps channel for the endoscope to be an external forceps channel one side of which is connected with the rod guide portion that is insertable into any of the C-shaped-cross-section groove and the protruding guide member and slidably insertable into and detachable from the cross-section of any of the C-shaped-cross-section groove and the protruding guide member, and wherein a guide wire as a core is provided in a central portion of the rod guide portion.

40. Schendel teaches an external forceps channel for an endoscope 62 is an external forceps channel 62 one side of which is connected with a rod guide 52,59 portion that is insertable into any of a C-shaped-cross-section groove 50 (fig. 12) and a protruding guide member 64 and slidably insertable into and detachable from the cross-section of any of a C-shaped-cross-section and the protruding guide member 64 (fig. 12), and wherein a guide wire 51 as a core is provided in a central portion of the rod guide portion 59 of 52 (col. 4, lines 52-55).

41. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Stefanchik in view of Cooper, further in view of the limitations taught by Schendel in order to provide an endoscopic apparatus having a radially flexible clip coupled to the insertion portion of the endoscope in order to selectively provide or exchange working channels with variable cross-sections while the insertion portion is within the patient's body.

42. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik 2004/0230095 in view of Cooper 4,667,229 further in view of Kehr 2002/0049366.

43. Stefanchik in view of Cooper disclose the invention as discussed above. Stefanchik further discloses the external forceps channel device for an endoscope 20 adopts a structure in which a tunnel 93 is provided under a surface of the insertion portion of the endoscope 100 along the surface in its longitudinal direction.

44. However, Stefanchik in view of Cooper do not disclose a freely movable magnetic body to be provided in the tunnel, another magnetic body to be also provided at a bottom portion of a tube through which forceps are inserted along the outside of the insertion portion of the endoscope, and when inserting the external forceps channel device, the device is inserted while being guided by the movable magnetic body.

45. Kehr teaches a freely movable magnetic body 58 [0092] is provided in a tunnel, another magnetic body 56 [0092] to be also provided at a bottom portion of a tube.

46. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device Stefanchik in view of Cooper, further in view of the limitations taught by Kehr in order to provide a device for positioning at least one component within an

endoscopic system utilizing smaller number of movable parts, reducing the danger of functional defects, as taught by Kehr [0014 et seq. 0042].

47. With respect to the recitation "a tunnel is provided immediately under a surface of the insertion portion of the endoscope", it would have been obvious to one of ordinary skill in the art at the time of the invention to have positioned the tunnel or channel 93 within endoscope 100 such that it's top surface was directly beneath the surface of the endoscope housing since it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

Conclusion

48. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Herrmann 6,878,106; Silverstein 5,025,778.**

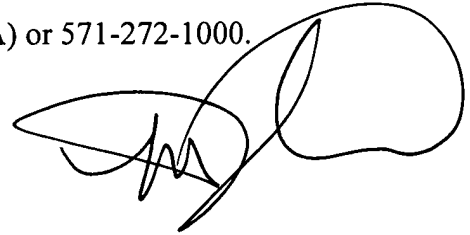
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alireza Nia whose telephone number is 571-270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alireza Nia
November 30th, 2007



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